

FORM HCFA-179 (07-92)

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DIVISION 5A

MINNESOTA
MEDICAL ASSISTANCE

Federal Budget Impact of Proposed State Plan Amendment TN 03-36
Attachments 3.1-A/B: Prescribed Drugs

The Centers for Medicare & Medicaid Services, Pharmacy Team (PharmT) informed the Department that any changes to the Department's approved Supplemental Rebate Agreement requires updating the State plan.

The agreement is updated to make it a "one size fits all" model agreement, with added assurances for manufacturers and another rebate calculation option. Therefore, TN 03-36 updates the supplemental drug rebate agreement language on page 46e of Attachment 3.1-A and on page 45e of Attachment 3.1-B.

The Department estimates that there will be no federal budget impact. The fact that the Supplemental Rebate Agreement is updated does not alter how much savings the state may achieve as a result of approval of the first agreement on January 3, 2003.

The Department anticipates that no recipients will be impacted by TN 03-36. The fact that the Supplemental Rebate Agreement is updated does not alter the estimate of the number of recipients impacted as a result of approval of the first agreement.

12.a. Prescribed drugs.

The following providers are eligible for payment for dispensing prescribed drugs:

- (1) A pharmacy that is licensed by the Minnesota Board of Pharmacy.
- (2) An out of state pharmacy that complies with the licensing and certification requirements of the state in which it is located.
- (3) A physician located in a local trade area where there is no Medicaid enrolled pharmacy. To be eligible for payment, the physician shall personally dispense the prescribed drug according to applicable Minnesota Statutes and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
- (4) A physician or nurse practitioner employed by or under contract with a community health board, for the purposes of communicable disease control.

The following limitations apply to pharmacy services:

- (1) With the exception noted below, the prescribed drug must be a drug or compounded prescription that is made by a manufacturer that has a rebate with the Centers for Medicare & Medicaid Services (CMS) and included in the Minnesota Department of Human Services drug formulary. The formulary is established in accordance with §1927 of the Social Security Act. See Drug Formulary.
 - A prescribed drug is covered if it has Investigational New Drug (IND) status with an IND number by the United States Food and Drug Administration (FDA), even though the manufacturer does not have a rebate with CMS. When the prescribed drug receives FDA approval, the manufacturer must have a rebate agreement for the drug in order for the drug to be covered.
- (2) A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing, the specified quantity is not available in the pharmacy when the prescription is dispensed, or the specified quantity exceeds a 34-day supply.

12.a. Prescribed drugs. (continued)

- (3) Effective October 1, 2003, the dispensed quantity of a prescribed drug must not exceed a 34-day supply, unless authorized by the Department. The following do not require prior authorization:
 - (a) over-the-counter medications must be dispensed in the manufacturer's unopened package, and Sorbitol may be repackaged.
 - (b) contraceptive drugs may be dispensed in quantities not exceeding a 90-day supply.
- (4) An initial or refill prescription for a maintenance drug shall be dispensed in not less than a 30-day supply unless the pharmacy is using unit dose dispensing. No additional dispensing fee shall be paid until that quantity is used by the recipient.
- (5) Except as provided in item (6), coverage of the dispensing fee for a particular pharmacy or dispensing physician for a maintenance drug for a recipient is limited to one fee per 30-day supply.
- (6) More than one dispensing fee per calendar month for a maintenance drug for a recipient is allowed if:
 - (a) the record kept by the pharmacist or dispensing physician documents that there is a significant chance of overdose by the recipient if a larger quantity of drug is dispensed, and if the pharmacist or dispensing physician writes a statement of this reason on the prescription; or
 - (b) the drug is clozapine.
- (7) A refill of a prescription must be authorized by the practitioner. Refilled prescriptions must be documented in the prescription file, initialed by the pharmacist who refills the prescription, and approved by the practitioner as consistent with accepted pharmacy practice under Minnesota Statutes.

12.a. Prescribed drugs. (continued)

- (8) Generic drugs must be dispensed to recipients if:
 - (a) the generically equivalent drug is approved and is determined as therapeutically equivalent by the FDA;
 - (b) in the pharmacist's or dispensing physician's professional judgment, the generically equivalent drug is safely interchangeable with the prescribed drug;
 - (c) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed; and
 - (d) the practitioner has not written in his or her own handwriting "Dispense as Written-Brand Necessary" or "DAW-Brand Necessary" on the prescription.
- (9) The following limits apply to drugs dispensed under unit dose packaging:
 - (a) Dispensing fees for drugs dispensed in unit dose packaging shall not be paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees.
 - (b) Only one dispensing fee per calendar month will be paid for each maintenance drug, regardless of the type of unit dose system used or the number of times during the month the pharmacist dispenses the drug.
 - (c) An additional dispensing fee per prescription shall be paid to pharmacists using an in-pharmacy packaged unit dose system (except for over-the-counter medications) approved by the Board of Pharmacy for the return of drugs when dispensing to recipients in a long-term care facility if:
 - (i) the pharmacy is registered with the Department by filing an addendum to the provider agreement;

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12.a. Prescribed drugs. (continued)

- (ii) a minimum 30-day supply of the drug is dispensed, although a lesser quantity may be dispensed for an acute course of medication therapy for a specified time period;
- (iii) the national drug code from the drug stock container used to fill the unit dose package is identified to the Department;
- (iv) the unit dose package containing the drug meets the packaging standards set forth in Minnesota Statutes that govern the return of unused drugs to the pharmacy for reuse and documentation that unit dose packaging meets permeability standards of the Board of Pharmacy; and
- (v) the pharmacy provider credits the Department for the actual acquisition cost of all unused drugs that are eligible for return and reuse.

(10) Delivery charges for a drug are not covered.

Drug Formulary:

All drugs and compounded prescriptions made by a manufacturer that are covered under a signed rebate agreement with CMS are included in the drug formulary, with the following limitations on coverage:

- (1) The following over-the-counter drugs are covered only when prescribed by a licensed practitioner or a licensed pharmacist who meets standards established by the Department, in consultation with the Board of Pharmacy:
 - (a) antacids;
 - (b) acetaminophen;
 - (c) aspirin;
 - (d) family planning products;
 - (e) insulin;
 - (f) products for the treatment of lice;
 - (g) vitamins for adults with documented vitamin deficiencies;

12.a. Prescribed drugs. (continued)

- (h) vitamins for children under the age of seven and pregnant or nursing women; and
 - (i) any other drug identified by the Department, in consultation with the Drug Formulary Committee.
- (2) The following categories of drugs are not covered pursuant to §1927(d)(2):
 - (a) Effective August 1, 2003, drugs used for weight loss, except that medically necessary lipase inhibitors may be covered for recipients with type 2 diabetes.
 - (b) Agents when used to promote fertility.
 - (c) Agents when used for cosmetic purposes or hair growth.
 - (d) Covered outpatient drugs that the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
 - (e) Drugs described in §107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of 21 CFR §310.6(b)(1) (DESI drugs)).
- (3) The following categories of drugs are covered with limitations pursuant to §1927(d)(2):
 - (a) Agents when used for the symptomatic relief of cough and colds must be listed in the Department's "Minnesota Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.
 - (b) Nonprescription drugs must be listed in the Department's "Health Care Programs Provider Manual," on a remittance advice message, or in a Department-issued provider update.

12.a. Prescribed drugs. (continued)

- (c) Prescription vitamins and mineral products for children, pregnant and nursing women, and recipients with documented vitamin deficiencies. The limitations do not apply to fluoride treatments. Prenatal vitamins are restricted to pregnant and nursing women.

Notwithstanding the above paragraph, some vitamins and mineral products are available for the treatment or prevention of certain diseases:

- (1) niacin;
- (2) calcium and calcium/vitamin D; and
- (3) generic preparations equivalent to Ocuvite.

Prior Authorization:

- A. The following requirements, found in §1927(d)(5) of the Act, are met:
- The prior authorization program provides a response by telephone or other telecommunication device within 24 hours of a request
 - The prior authorization program provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation (except for those drugs that are excluded or restricted from coverage, as noted above)
- B. Based on the requirements in §1927, the State has the following policies for the supplemental drug rebate program for Medicaid recipients:
- 1) The model rebate agreement between the State and drug manufacturers for drugs provided to Medicaid recipients, submitted to CMS on ~~September 30, 2002~~ December 2, 2003 and entitled "State of Minnesota Supplemental Rebate Agreement," has been approved by CMS.
 - 2) Supplemental drug rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national drug rebate agreement.

STATE: MINNESOTA
Effective: October 1, 2003
TN: 03-36
Approved: MAR 01 2004
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ATTACHMENT 3.1-A
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12.a. Prescribed drugs. (continued)

- 3) A drug that the Department determines comes within its supplemental drug rebate program for Medicaid recipients as allowed by §1927, but for which a manufacturer has not signed a supplemental drug rebate agreement approved by CMS, will be prior authorized.
- Even if a manufacturer has not signed a supplemental drug rebate agreement, when there is no generically equivalent drug available, there is never prior authorization for:
 - a) any antihemophilic factor drug prescribed for the treatment of hemophilia and blood disorders; and
 - b) any atypical antipsychotic drug prescribed for the treatment of mental illness if the drug was initially prescribed for the recipient before July 1, 2003 or the drug is part of the recipient's current course of treatment.

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 - A prescribed drug is covered if it has Investigational New Drug (IND) status with an IND number by the United States Food and Drug Administration (FDA), even though the manufacturer does not have a rebate with CMS. When the prescribed drug receives FDA approval, the manufacturer must have a rebate agreement for the drug in order for the drug to be covered.
- (2) A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing, the specified quantity is not available in the pharmacy when the prescription is dispensed, or the specified quantity exceeds a 34-day supply.